DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, and 424

[CMS-1321-P]

RIN 0938-AO24

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would address certain provisions of the Deficit Reduction Act of 2005, as well as make other proposed changes to Medicare Part B payment policy.

We are proposing these changes to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. This proposed rule also discusses geographic practice cost indices (GPCI) changes; requests for additions to the list of telehealth services; payment for covered outpatient drugs and biologicals; payment for renal dialysis services; policies related to private contracts and opt-out; policies related to bone mass measurement services, independent diagnostic

specified in §414.804(a)(3)(i).

Our proposed methodology for excluding lagged exempted sales is similar to the methodology manufacturers are required to use to estimate price concessions known on a lagged basis, and was recommended by manufacturers. We believe requiring similar methods to estimate both lagged exempted sales and lagged price concessions is reasonable and reduces potential errors in the manufacturers' ASP calculations, while ensuring that exempted sales are appropriately removed from the ASP calculation. In addition, using an estimation methodology to remove lagged exempted sales reduces the likelihood of quarter to quarter variations in the ASP.

We seek comments on the proposed methodology for excluding exempted sales known on a lagged basis from the ASP calculation and estimate of lagged price concessions. We also solicit suggestions on appropriate alternative methodologies that may be less complex.

c. Nominal Sales

Section 1847A(c)(2)(B) of the Act requires manufacturers to exclude from the ASP calculation sales that are merely nominal in amount, as applied for purposes of section 1927(c)(1)(C)(ii)(III) of the Act, except as the Secretary may otherwise provide. Effective

January 1, 2007, the DRA (Pub.L. 109-171) modifies section 1927(c)(1)(C)(ii)(III) of the Act. Limitations on nominal sales have been added in new section 1927(c)(1)(D) of the Act. The DRA also modified the average manufacturer price (AMP) calculation and frequency of AMP reporting. Therefore, we are proposing to clarify the method manufacturers must follow, beginning in 2007, to identify nominal sales for ASP reporting purposes and to exclude nominal sales from the calculation of the ASP. We also are seeking comments on whether we should establish an alternative definition of nominal sales for ASP purposes.

In the preamble to the ASP reporting interim final rule, we stated sales to an entity that are nominal in amount are defined in the Medicaid drug rebate agreement (see sample agreement at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf). That is, for ASP purposes, a nominal sale is a sale at a price less than 10 percent of the AMP in the same quarter for which the AMP is computed. Effective January 1, 2007, the DRA revises the AMP calculation (to omit customary prompt pay discounts extended to wholesalers), added a monthly AMP reporting requirement, and established limitations on nominal sales (only sales to certain entities may qualify as nominal

sales). Section 1927(c)(1)(D) of the Act limits the nominal sales exclusion to nominal sales made to the following entities:

- 340B covered entities as described in section 340B(a)(4) of the Public Health Services Act (PHS Act).
- Intermediate care facilities for the mentally retarded (ICFs/MR).
- State-owned or operated nursing facilities.
- Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate based on the factors described in section 1927(c)(1)(D)(ii) of the Act.

Because section 1847A(c)(2)(B) of the Act requires manufacturers to exclude from the ASP calculation sales that are merely nominal in amount, as applied for purposes of section 1927(c)(1)(C)(ii)(III) of the Act, except as the Secretary may otherwise provide, the DRA changes will have implications for ASP reporting beginning January 1, 2007 (unless we provide an alternative policy for determining nominal sales as permitted under section 1847A(c)(2)(B) of the Act). One implication is that the limitations set forth in section 1927(c)(1)(D) of the Act will continue the exclusion of nominal sales to certain entities while requiring that sales to entities not identified under

section 1927(c)(1)(D) of the Act are included in the ASP calculation, even if such sales are at very low prices. Another implication is the AMP calculation will exclude customary prompt pay discounts extended to wholesalers, yet prompt pay discounts will continue to be a type of price concession that manufacturers must include in their ASP calculations. The change in treatment of customary prompt pay discounts extended to wholesalers in the AMP calculation may result in a higher number of sales that are at less than 10 percent of the AMP than in past ASP reporting periods (notwithstanding the new limitation on what is considered a nominal sale under section 1927(c)(1)(D) of the Act). Still another implication is that the frequency of AMP reporting will include monthly reporting; thus, for ASP purposes, there is further need to clarify how nominal sales are to be identified in 2007. Separate Medicaid rulemaking will address the DRA provisions related to AMP reporting.

We believe the DRA modifications to section 1927 of the Act noted above will have minimal effect on reported ASPs. We would expect that the exclusion of customary prompt pay discounts extended to wholesalers from AMP would lead to a modest increase in AMP, and as a result a modest increase in the number of sales that would qualify as

nominal under the current ASP reporting regulations. At the same time, we anticipate that the limitation on nominal sales in section 1927(c)(1)(D) of the Act will result in a modest reduction in the number of sales that qualify as nominal sales for purposes of ASP reporting because we believe that the entities outlined in section 1927(c)(1)(D) of the Act generally represent the types of entities to which manufacturers may offer sales at a nominal amount. Consequently, we would expect these two countervailing changes would have a minimal overall impact on nominal sales that would be excluded from the ASP calculation. For 2007 and beyond, we propose to revise §414.804(a)(4) to clarify that manufacturers must continue to use the Medicaid threshold (less than 10 percent of AMP) to determine nominal sales that are excluded (subject the limitations in section 1927(c)(1)(D) of the Act) from the ASP calculation. Further, we propose that, in identifying nominal sales, manufacturers must use the AMP for the calendar quarter that is the same calendar quarter for the ASP reporting period. For these reasons, we are proposing to continue the current methodology for identifying and excluding nominal sales (that is, sales that are exempt from the Medicaid best price calculation under section 1927(c)(1)(C)(ii)(III) of the Act) from the manufacturer's

calculation of the ASP. We believe this approach helps maintain continuity in the ASP calculation and minimizes manufacturers' reporting burden, as Medicare continues to follow the Medicaid approach for identifying nominal sales and manufacturers can use a single method for identifying nominal sales for both ASP and AMP purposes.

We seek comments on our proposal to continue use of the AMP as the basis for identifying nominal sales excluded from the ASP calculation and on whether an alternative threshold for identifying nominal sales for ASP calculation purposes is necessary or desirable to ensure the accuracy of the ASP payment methodology. Specifically, we seek comments on whether sales at less than 10 percent of the ASP (instead of the AMP) should be used to identify nominal sales for ASP purposes (with the new requirement in section 1927(c)(1)(D) of the Act allowing only sales to certain entities to be considered nominal sales still being applicable). We also seek comments on our belief that the new limitations on nominal sales and change to the AMP calculation will have minimal impact on reported ASPs.

Subsequent to the April 6, 2004 IFC, we received requests for clarification on a technical aspect related to the identification of nominal sales. Specifically, some manufacturers have asked whether nominal sales are

identified by performing a series of calculations once or whether the manufacturer repeats the series of calculations until no remaining ASP eligible sales are below the nominal threshold. Consistent with current Medicaid reporting, for 2005 and 2006, manufacturers must identify nominal sales by performing the following steps once:

- The manufacturer calculates the AMP for the reporting quarter to identify the dollar amount that represents 10 percent of the AMP for that reporting period.
- The manufacturer then identifies sales below this amount and excludes these sales from the ASP calculation.
- Beginning in 2007, the limitations in section 1927(c)(1)(D) of the Act must also be met to exclude the sale.

d. Other Price Concession Issues

In our ongoing work with manufacturers that submit ASP data, some manufacturers have posed questions or raised concerns about how the estimate of lagged price concessions is done prior to having 12 months of data for a NDC and, when a product is redesignated with a new NDC, whether price concessions from the prior NDC must be included in calculating the ASP for the new NDC. Manufacturers and other stakeholders have also asked us about how Medicare’s ASP guidance concerning price concessions is to be applied